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10/590,959	03/12/2007	Doo Sung Lee	Q96860	5634
23373	7590	07/07/2009	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			JONES JR., ROBERT STOCKTON	
ART UNIT	PAPER NUMBER			
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07/07/2009	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,959	Applicant(s) LEE ET AL.
	Examiner ROBERT JONES JR.	Art Unit 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08e)
 Paper No(s)/Mail Date 08/29/2006, 03/12/2007
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

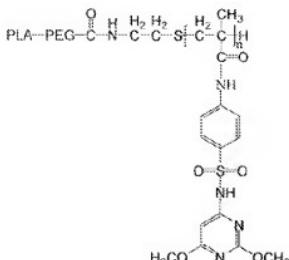
5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Han et al. (*Colloids & Surfaces A: Physiochem. Eng. Aspects*, 2003, 49-59).

15 Regarding Claims 1-6, Han teaches a block copolymer comprising poly(ethylene glycol) (PEG), poly(L-lactic acid) (PLLA; a biodegradable polymer; Claims 4-5), and an oligomeric poly(sulfadimethoxine) (PSD; a sulfonamide-based oligomer) formed by coupling a PLA-PEG diblock copolymer with PSD (p. 51, scheme 1, (c)). According to Han's Scheme 1, said PSD possesses a terminal amine group (Claim 7) prior to forming
20 the block copolymer. The resulting block copolymer is illustrated below:



PLLA/PEG-PSD

In the above formula, n is equal to 10. When n=10, the molecular weight of the sulfonamide oligomer is 835 (Claim 9). Said PEG has a molecular weight of 2000 (Claim 3; p. 50, section 2.1). This corresponds to Formula 1 in Claim 2, wherein n=45.

- 5 Said PLA has a molecular weight of 3500 (p. 52, col. 1, lines 17-18). Thus, the weight ratio of PEG to PLA is 1:1.75 (Claim 6).

Claim Rejections - 35 USC § 103

- 10 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 5 1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation 15 under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20 Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han as applied to Claim 1 above, further in view of Huang et al. (*Macromol. Chem. Phys.*, 2003, p. 1994-2001).

Han remains as applied to Claim 1 above. Han's block copolymer is effectively a carrier for sulfadimethoxine, a sulfonamide drug. Sulfonamide drugs are 25 chemotherapeutic agents employed for the prevention and cure of bacterial infection (p. 50, col. 1, para. 4). Han does not teach a triblock or higher order multiblock copolymer.

In the field of block copolymer-based drug delivery, Huang teaches block copolymers with PEG, PLA, and poly(caprolactone) (PCL) segments (Abstract). PCL is a biocompatible and biodegradable polymer with high permeability to drugs, and additionally possesses a low melting temperature and high decomposition temperature.

- 5 Thus, PCL has a wide processing range (p. 1, Introduction, lines 8-12). Huang's copolymers conserve the excellent thermal behavior inherent to PCL, thus providing a wide range of processing temperatures for thermal treatments (p. 2000, col. 2, lines 2-6). Huang's copolymers include a pentablock PLA-PCL-PEG-PCL-PLA, and a triblock mPEG-PCL-PLA (mPEG = monohydroxyl poly(ethylene glycol)) (p. 1995, Results and
- 10 Discussion; p. 1996, Table 1).

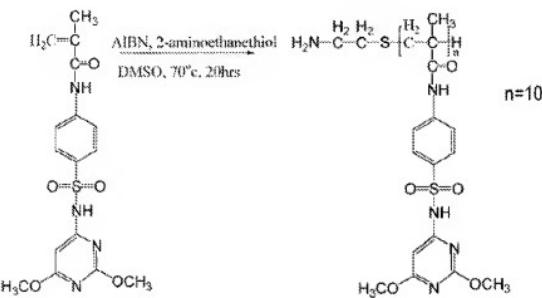
It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Han in view of Huang to replace Han's PEG-PLA copolymer with either Huang's PLA-PCL-PEG-PCL-PLA pentablock or mPEG-PCL-PLA triblock copolymer. Such modification would serve to incorporate one or more PCL blocks into

15 Han's PEG-PLA copolymer, and would result in a lower melting temperature, a higher decomposition temperature, and thus a wider processing range. Additionally, incorporation of PCL will impart PCL's higher permeability to drugs, which is desirable in view of the fact that Han's copolymer serves as a means of delivery for a sulfonamide drug.

- 20 Modification of Han in view of Huang would result in a triblock or pentablock copolymer of PEG with two biodegradable polymers (PLA and PCL) and a sulfonamide-based oligomer. Thus, all requirements of Claims 10 and 11 are satisfied.

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One of ordinary skill in the art will recognize that in order to effectively couple Han's PSD to Huang's triblock or pentablock copolymer, further modification is necessary. Han's Scheme 1 illustrates an amine-functional oligomer, seen here (p. 51, Scheme 1, (b)):

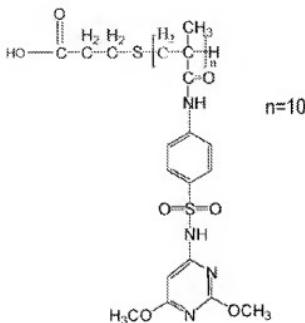


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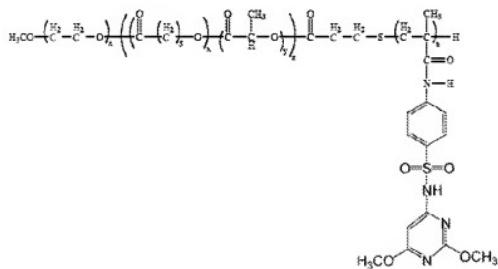
However, Huang's copolymers, comprising PLA end blocks, will inherently be hydroxyl-functional, while Han's PSD is amine-functional. Thus, it is necessary to incorporate an end group into the above PSD that is reactive with a hydroxyl moiety. It is well known that carboxylic acids and their derivatives possess the desired reactivity.

- 10 In order to maintain equivalent functionality and retain the 2-carbon chain between the thioether and functional group, one of ordinary skill in the art would at once envisage the use of mercaptopropionic acid in place of 2-aminoethanol in the scheme above to arrive at the PSD oligomer shown below:

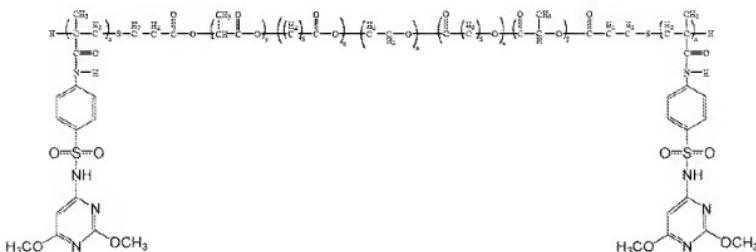
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In view of the necessary modification to the PSD oligomer, modification of Han in view of Huang will result in the triblock or pentablock copolymers seen here:



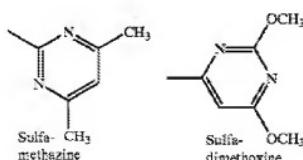
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Claims 8 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han in view of Huang as applied to claims 1, 10, and 11 above, and further in view
5 of Bae et al. (US Pat. No. 6,103,865).

Han in view of Huang remains as applied to Claims 1, 10, and 11 above. Neither Han nor Huang teach the sulfonamide compound of Claim 8, or copolymers conforming to Formulas 2, 3, and 4 of Claims 12, 13, and 14, respectively.

In the field of sulfonamide-containing polymers, Bae discloses a number of
10 equivalent sulfonamides (col. 3-4, Table 1). Bae's sulfonamides include sulfadimethoxine and sulfamethiazine, illustrated below:



It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Han in view of Huang as discussed above. It would have been obvious to further modify Han in view of Bae to replace the sulfadimethoxine residue of Han's oligomer with sulfamethiazine, as the two are described as alternatives to one

- 5 another and are functionally equivalent. The resulting modification will yield a pentablock copolymer satisfying the structural requirements of Claim 12, or a triblock copolymer satisfying the structural requirements of Claim 13, illustrated below:

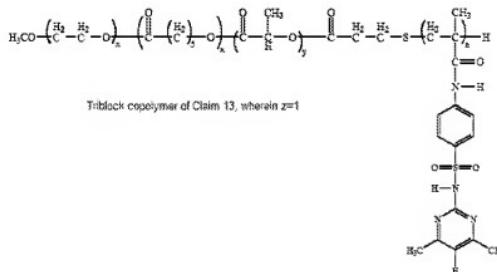
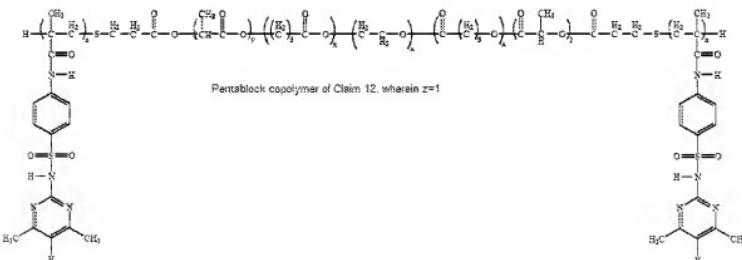
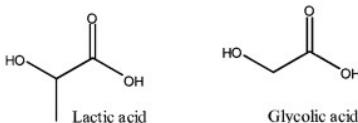


Table 3: continuation of Claim 13, wherein $\gamma = 1$



Reversible co-coupling of Claim 12, wherein $\tau=1$

Regarding Claim 14, neither Han, Huang, nor Bae teach a pentablock copolymer similar to that pictured above wherein the lactic acid residues are replaced with glycolic acid residues. Lactic and glycolic acids have the structure seen below:



- 5 The two differ by a single carbon, are functionally equivalent, and it is well known and established in the art that both polylactic acid and polyglycolic acid are biodegradable. Thus, lactic acid and glycolic acid are considered to be structurally similar, differing by a methyl group only.

Therefore, it would have been obvious to one of ordinary skill in the art at the 10 time of the invention to further modify the pentablock copolymer resulting from Han in view of Huang and Bae to replace the PLA segment with a polyglycolic acid segment, as the two are structurally similar and therefore functional equivalents. Using glycolic acid instead of lactic acid would still provide biodegradable polymer that can be utilized in the same manner as that of Han.

15

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Han as applied to Claim 1 above, further in view of Shah (US Pat. No. 6,541,033).

Regarding Claim 1, Han remains as applied above. Han does not teach a 20 hydrogel composition comprising a block copolymer as claimed in Claim 15, or a hydrogel formed from said hydrogel composition.

In the field of biodegradable block copolymer-based drug delivery, Shah teaches forming hydrogels from block copolymers comprising PLA or poly(lactide-co-glycolide) (PGLA) and PEG, for the sustained delivery of biologically active agents (Abstract).

Shah further teaches that biodegradable block copolymers formed from PEGs with

- 5 molecular weights ranging from 200 to 2000, and PLA or glycolic acid (GA) with
molecular weights ranging from 400 to 5000 formed hydrogels (col. 2, line 67 – col. 3,
line 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to form a hydrogel comprising Han's PLA-PEG-sulfonamide for the benefit of
10 providing sustained release for the sulfonamide-based drug portion of the molecule.
Said hydrogel is also intrinsically a hydrogel composition.

Conclusion

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
20 supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

- 5 For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10

/Katarzyna Wyrozebski/
Primary Examiner, Art Unit 1796

RSJ